

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to Figure 9. This sheet, which includes Figures 9 and 10, replaces the original sheet including Figures 9 and 10.

Attachment: Replacement Sheet

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-28 are pending in this application, of which claims 11-20 are withdrawn as being directed to a non-elected invention. By this Amendment, claims 1-10 and 21-28 are amended. No new matter is added. Claims 1 and 26 are the independent claims.

Applicants note with appreciation the Examiner's acknowledgement that certified copies of all priority documents have been received by the U.S.P.T.O.

Applicants also appreciate the Examiner's indication that the Information Disclosure Statements filed on April 30, 2008, August 16, 2007, February 2, 2007, and July 28, 2006, have been considered.

Applicants also respectfully note that the present action does not indicate that the drawings have been accepted by the Examiner. Applicants respectfully request that the Examiner's next communication include an indication as to the acceptability of the filed drawings or as to any perceived deficiencies so that the Applicants may have a full and fair opportunity to submit appropriate amendments and/or corrections to the drawings.

Election/Restriction Requirement

Applicants acknowledge the election of Group 1, of which claims 1-10 and 21-28 read on, and claims 11-20 have been withdrawn by the Examiner as being directed to a non-elected invention.

Applicants respectfully reserve the right to file a divisional application(s) directed to the non-elected invention, *viz.* claims 11-20.

Objection to the Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because Figure 9 includes reference characters not mentioned in the description. Applicants respectfully traverse this rejection for the reasons discussed below.

In particular, the reference characters correspond as follows:

- “4a” – working electrode (WE)
- “4b” – reference electrode (Ref)
- “4c” – counter electrode (CE)
- “11i” – lower side of the transducer array
- “U_{out}” – signal pattern
- “t” – time
- “3_i” – circular depressions.

In regard to reference characters “10_i”, “20_i” and “110”, Applicants have removed these reference characters in FIG. 9 and/or amended the instant disclosure, to obviate the objections.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the objection to the drawings.

Claim Rejections - 35 U.S.C. § 112

I. First Paragraph

Claims 1, 2-10, 21-25, and 28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection for the reasons discussed below.

In rejecting claim 1 for lack of enablement, the Examiner asserted,

the amount of direction provided by the inventor does not provide one skilled in the art the ability to arrive at a specific pulse length or provide one skilled in the art with a method by which a pulse length is selected. In the instant case, it is not clear from the specification how pulse lengths are chosen which is what is being claimed. In section [0056] of applicant's PG Pub Document, it appears that applicant has "set" the pulse lengths at times .25 and .75 seconds and has not provided clear criteria as to how these variables were arrived at which is the crux of claim 1....¹

Applicants respectfully submit that this rejection is improper, and respectfully submit that the method presently recited in claim 1 is fully enabled by the instant application as originally filed.

For instance, there are various examples in the instant disclosure on how pulse lengths can be chosen - see e.g., description of the figures and claims. Although, it may not be possible to define the pulse lengths exactly for all possible cases, since it depends on the system (chemical and physical set up), the instant disclosure adequately and sufficiently describes how the pulse lengths are chosen for the examples provided therein. For example, claim 1 defines how the length may be chosen by, "selecting ... the measuring-phase pulse lengths so that, towards the end of the pulse, the capacitive current is relatively small in comparison with the Faraday current" and "selecting the relaxation-phase pulse lengths so that, towards the end of the pulse, the concentration gradient is relaxed so that at the beginning of a following measuring phase, the change in concentration of the mediator, brought about by the consumption of the mediator by the measurement itself, is reversible to the greatest possible extent."

¹ Office Action mailed September 17, 2010, paragraph bridging pages 4 and 5.

Accordingly, as described in the instant disclosure, the values (e.g., pulse lengths) may be derived from the current measurements. A skilled person in the art knows how to choose the values, measuring a current for a system of interest, and chose from the time dependence of the current the values for the pulses, which can then be used for the final measurements – *see at least FIG. 3*.

Therefore, contrary to the Examiner's assertion, the originally filed disclosure does provide one skilled in the art the ability to arrive at a specific pulse length or provide one skilled in the art with a method by which a pulse length to be selected. Accordingly, the scope of *at least* claim 1 is entirely commensurate with, and is fully enabled by, the original disclosure.

In addition, in regard to FIGS. 5 and 6, the Examiner asserted,

applicants notes that a measurement is being taken over a 10 second time period; however, it is not clear what these time periods represent. Are they the time of the measurement/relaxation phase?.....

Additionally, with regard to figures 5 and 6, numerals 51-54 and 61-64 are the results of different relaxation phase durations. There is no indication of which one is preferred or as to how one skilled in the art would select an appropriate relaxation phase duration²

Applicants submit that Figures 5 and 6 adequately describe the appropriate relaxation phase duration, and respectfully submit that it is well within the ability of one of ordinary skill in the art to perform the method, without undue experimentation. That is, with regard to Figures 5 and 6, it is respectfully submitted that there is no indication which relaxation phase duration is preferred, but describes only an example how the measurement fault depends on the duration. For example, claim 5 recites that there is a value of 1/10Hz given, in which 1 Hz may provide a

² Office Action mailed September 17, 2010, pages 5 and 6.

measurement fault of 1% in the described example, so 1/10 Hz may provide much less measurement fault. Accordingly, one skilled in the art can choose, with the given values and relations in Figures 5 and 6 (depending on the system and necessary measurement accuracy), the pulse lengths.

Accordingly, Applicants respectfully submit that the rejection of claim 1 for lack of enablement is improper.

Therefore, since it is well within the ability of one of ordinary skill in the art to perform the method recited in claim 1 without undue experimentation, Applicants respectfully submit that there is no reasonable basis for maintaining this rejection. Therefore, Applicants respectfully request that this rejection of claim 1, and of claims 2-10, 21-25, and 28 depending therefrom, be reconsidered and withdrawn.

II. Second Paragraph

Claims 1, 2-10, 21-25, and 28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection for the reasons discussed below.

Applicants have amended the claims, taking into consideration the Examiner's comments, to obviate the rejections.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, are respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 1-4 and 28 are rejected under 35 U.S.C. § 102(b) as being anticipated by J. Electroanal. Chem. 287, 1990, 349-362 to Gunasingham et al. (hereinafter "Gunasingham"). Applicants respectfully traverse this rejection for the reasons discussed below.

Applicants respectfully submit that the Gunasingham reference fails to disclose or suggest each and every element of claim 1, and therefore, an anticipatory rejection has not been established.³

For example, claim 1, recites a method for selecting pulse lengths for measuring at least one of a concentration and change in concentration of a redox-active substance.... in which as a result of application of suitable potentials....a reduction process or an oxidation process takes place as a redox process, comprising, *inter alia*:

pulsing the potential of the working electrode, and alternately forming measuring phases and relaxation phases.....

selecting the relaxation-phase pulse lengths so that, at the end of the pulse, the concentration gradient is relaxed so that at the beginning of a following measuring phase, the change in concentration of the mediator, brought about by the consumption of the mediator by the measurement itself, is reversible.

In other words, claim 1 recites that the redox reaction takes place between a reduction process "or" an oxidation process but at different times - at one time during a reduction process (happening at a reducing potential) or an oxidation process (happening at an oxidation potential). In addition, claim 1 recites that (in connection with measuring-phase and relaxation-phase) there has to be an oxidation potential pulse followed by a pulse at a reducing potential or vice versa in the measuring-phase

³ A claim is anticipated only if each and every element as forth in the claim is found, either expressly or inherently described, in a single prior art reference. See MPEP § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

and relaxation-phase, due to the limitation “change in concentration of the redox-active substance” and “concentration ... largely reversed” in claim 1, because if not there would be no redox reaction and no change in concentration of the redox-active substance which is reversed. Hence, claim 1 recites that there is an oxidation potential pulse followed by a pulse at a reducing potential or vice versa.

The Gunasingham reference, on the other hand, describes a totally different method as compared to the method of claim 1. Specifically, because Gunasingham discloses a flow system or uses an automated flow injection system (*see page 352*), it is submitted that the consumed substance (i.e., glucose) by the reduction or oxidation process flows away (is transported away) from the working electrode. Further, Gunasingham discloses that the electrode is made of Pt or glassy carbon, and an enzyme (glucose oxidase) is deposited on the electrode and bound by a mediator (i.e., tetrathiafulvalene TTF) to the electrode surface. However, it is submitted that the “mediator” of Gunasingham is a substance that allows a good electron transport from the enzyme to the electrode material Pt or glassy carbon and which binds the enzyme to the electrode - the substance to be measured is glucose. Therefore, it is distinguishing between an oxidation and a reduction potential of TTF and glucose.

By contrast, the oxidation and reduction potential of claim 1 is related to the “redox-active substance” (also called “mediator”), whereas the substance in Gunasingham which concentration is measured is “glucose.” Further, to measure its reaction with the enzyme glucose oxidase, there is only an oxidation potential of glucose necessary. Used oxidized glucose is transported away from the electrode by the flow. In Gunasingham, there is nothing regarding the relation of the base potential (of Fig. 1) to the oxidation or reduction potential of measured substance glucose. The meaning of “redution potential” (*page 350 lines 17-19*) in Gunasingham

is related to the TTF which binds the enzyme to the electrode. In addition, as base potential, a reduction potential of TTF is used because reduced TTF binds more strongly to the electrode. If this potential is an oxidation or reduction potential to glucose, it will not matter. Accordingly, it is submitted that there is only an indication in Gunasingham that the oxidation potential of glucose is also an oxidation potential of TTF. But since TTF does not take part in the detected reaction of glucose, it will not be pertinent for the measuring phase. Moreover, Gunasingham discloses that the current from the oxidation or reduction of TTF is added to the measuring signal as error.

Thus, it is submitted that the different oxidation and reduction potentials described in Gunasingham of TTF (base potential in Fig. 1 is reduction potential of TTF) and glucose (pulse potential in Fig. 1 is oxidation potential of glucose at enzyme glucose oxidase electrode) fail to teach or suggest every element of claim 1. In claim 1, the oxidation and reduction potential are related to the measured redox-active substance mediator - not to compare to the mediator as taught in Gunasingham. Further, the pulsing between potentials oxidating the substance to be measured and potentials reducing the substance to be measured is not taught in Gunasingham. Even further, the length of the pulses, especially the length of the relaxation-phase pulse as long to reverse the oxidation of redox-active substance, are also not taught in Gunasingham.

Therefore, contrary to the Examiner's contention, the Gunasingham reference does not disclose or suggest each and every element of claim 1.

Since the Gunasingham reference fails to disclose each and every element of claim 1, it cannot provide a basis for a rejection under 35 U.S.C. § 102(b) and, thus, is

allowable. Claims 2-4 and 28 depend from amended claim 1 and, therefore, allowable for similar reasons to those discussed above with respect to claim 1.

For at least these reasons, the Examiner is respectfully requested to reconsider and withdraw the § 102(b) rejection of claims 1-4 and 28.

Claims 26 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Anal. Chem. 1989, 61 2566-2570 to Bindra et al. ("the Bindra reference"); and Claims 26 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,391,558 to Henkens et al. ("the Henkens reference"). Applicants respectfully traverse these rejections for the reasons discussed below.

For the similar reasons as discussed above regarding claim 1, Applicants respectfully submit that claim 26 is similarly allowable. In particular, claim 26 recites, *inter alia*:

a device for selecting pulse lengths for measuring at least one of a concentration and change in concentration of a redox-active substance as a mediator in a molecular-biological detection system, in which as a result of application of suitable potentials to a working electrode, at least one of a reduction process and an oxidation process takes place as a redox reaction, the device comprising:

a device for pulsing the potential of the working electrode, and alternately forming measuring phases and relaxation phases....

a device for selecting the relaxation-phase pulse lengths so that, at the end of the pulse, the concentration gradient is relaxed so that at the beginning of a following measuring phase, the change in concentration of the mediator, brought about by the consumption of the mediator by the measurement itself, is reversible.

Applicants respectfully submit that the Bindra and the Henkens references similarly fail to provide the teachings, discussed above, that are missing from the Gunasingham reference.

In view of the above, Applicants respectfully submit that the Bindra and the Henkens references fail to teach or suggest *all* of the elements of claim 26. Thus, no *prima facie* case of anticipation has been established. Accordingly, claim 26 is allowable over the Bindra and the Henkens references. Dependent claim 27 depends from claim 26 and is allowable for at least the reasons that claim 26 is allowable. Therefore, Applicants respectfully request that the rejection of claims 26 and 27 under 35 U.S.C. § 103(a) be favorable reconsidered and withdrawn.

Claim Rejections - 35 U.S.C. § 103

Claims 5, 10, and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gunasingham et al. in view of Bindra et al. Applicants respectfully traverse this rejection for the reasons discussed below.

Claims 5, 10, and 21 are believed to be allowable for at least the reasons set forth above regarding claim 1. The Bindra reference fails to provide the teachings noted above as missing from the Gunasingham reference. Since claims 5, 10, and 21 are patentable at least by virtue of their dependency on claim 1, Applicants respectfully request that the rejection of claims 5, 10, and 21 under 35 U.S.C. § 103(a) be withdrawn.

Claims 6-8 and 22-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gunasingham et al. in view of WO 01/21827 to Buck et al. ("the Buck reference"). Applicants respectfully traverse this rejection for the reasons discussed below.

Claims 6-8 and 22-24 are believed to be allowable for at least the reasons set forth above regarding claim 1. The Buck reference fails to provide the teachings noted

above as missing from the Gunasingham reference. Since claims 6-8 and 22-24 are patentable at least by virtue of their dependency on claim 1, Applicants respectfully request that the rejection of claims 6-8 and 22-24 under 35 U.S.C. § 103(a) be withdrawn.

Claims 9 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gunasingham et al. and Buck et al. in view of Bindra et al. Applicants respectfully traverse this rejection for the reasons discussed below.

Claims 9 and 25 are believed to be allowable for at least the reasons set forth above regarding claim 1. The Bindra reference fails to provide the teachings noted above as missing from the Gunasingham and Buck references. Since claims 9 and 25 are patentable at least by virtue of their dependency on claim 1, Applicants respectfully request that the rejection of claims 9 and 25 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above remarks and amendments, Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. Further, the above remarks demonstrate the failings of the outstanding rejections, and are sufficient to overcome the rejections. However, these remarks are not intended to, nor need they, comprehensively address each and every reason for the patentability of the claimed subject matter over the applied prior art. Accordingly, Applicants do not contend that the claims are patentable solely on the basis of the particular claim elements discussed above.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned, at the telephone number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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